



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,705	02/04/2002	Charles L. Sawyers	02307K-141317US	8401
20350	7590	05/12/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			TON, THAIAN N	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/067,705	Applicant(s) SAWYERS ET AL.	
	Examiner Thaia N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 2/23/05.  
2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 21-25 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1 and 21-25 is/are rejected.  
7) ☒ Claim(s) 22 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 2/28/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicants' Response and Amendment, filed 2/25/05, has been entered and considered. Claim 1 has been amended. Claims 2-20 are cancelled. Claims 21-25 are newly added. Claims 1, 21-25 are pending and under current examination.

### *Oath/Declaration*

The petition under 37 C.F.R. § 1.183 has been granted. See the petition decision, mailed 3/14/05. The new declaration, filed 2/28/05, is proper and has been entered.

### *Claim Objections*

Claim 22 is objected to because of the following informalities: the claim does not end in a period. Appropriate correction is required.

### *Drawings*

The drawings were received on 2/28/05. These drawings are acceptable.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and newly added claims 21-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-11 of U.S. Patent No. 6,365,797 B1 (published April 2, 2002). This rejection is maintained for reasons of record advanced in the prior Office action, mailed 8/23/04.

For each of the prior double patenting rejections, Applicants have responded that the subject matter is commonly owned by the Regents of the University of California, and that to the extent that the rejections apply to the amended claims, Applicants will gladly consider submitting an appropriate terminal disclaimer. See p. 6 of the Response.

The Examiner acknowledges Applicants' willingness to file the Terminal Disclaimer. As no Terminal Disclaimer of record has been filed, the rejection is maintained.

Claims 1 and newly added 21-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-4, 7-13, 16 and 17 of U.S. Patent No. 6,107,540 [published August 22, 2000]. This

rejection is maintained for reasons of record. This rejection is maintained because no Terminal Disclaimer of record has been filed.

Claims 1 and newly added claims 21-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Pat. No. 6,828,471 (issued 12/7/04), previously referred to as claims 21-27 of copending Application No. 10/062,925.

This rejection is maintained for reasons of record. This rejection is maintained because no Terminal Disclaimer of record has been filed. Note: The '925 application has now issued and thus, this rejection is no longer considered a provisional rejection.

Claims 1 and newly added 21-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed claims 21-27 of copending Application No. 10/062,738. This rejection is maintained for reasons of record. This rejection is maintained because no Terminal Disclaimer of record has been filed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 21-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7-14 of U.S. Patent No. 6,8155,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the '574 patent result in the instantly claimed mouse. Note that the '574 claims are directed to an "immune deficient mouse" which encompasses the SCID mouse of the instantly claimed invention.

The '574 patent is to methods of stimulating the progression of human prostate cancer from primary tumor formation to micrometastasis or macrometastasis by providing an immune deficient mouse comprising a human prostate cancer xenograft of locally advanced or metastatic prostate cancer, allowing the xenograft to grow for a time sufficient to permit detection of the prostate cancer cells in the implant site, and then allowing the xenograft to grow to permit the detection for prostate cancer cells external to the implant site in the mouse. Further embodiments are directed to subcutaneous implantation, intrabone implantation or intraprostatic implantation of the xenograft. The instant claims are directed to a SCID mouse having a human prostate cancer xenograft of locally advanced or metastatic prostate cancer, wherein the mouse recapitulates the development of primary tumors, micrometastasis, or formation of osteoblastic lesions characteristic of late stage prostate cancer. Thus, given the methods of the '574 patent, it would have been obvious that they would result in the instantly claimed mouse.

***Claim Rejections - 35 USC § 102***

The prior rejections of claim 1, under 35 U.S.C. 102(a) as being anticipated by Liu or Pretlow [*J. of Nat. Canc. Inst.*, 85:394-398 (1993), is withdrawn in view of Applicants' amendment to the claims, which now recite that the mouse is a SCID mouse.

*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Ram Shukla, SPE of Art Unit 1632, at (571) 272-0735. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*tnt*

Thaian N. Ton  
Patent Examiner  
Group 1632

*John Winters*  
AU 1632